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8  
9 UNITED STATES DISTRICT COURT

10 DISTRICT OF ARIZONA

11 In Re Bard IVC Filters Products  
12 Liability Litigation

No. MD-15-02641-PHX-DGC

13 SHERR-UNA BOOKER, an  
14 individual,

15 Plaintiff,

16 v.  
17 C.R. BARD, INC., a New Jersey  
corporation and BARD  
18 PERIPHERAL VASCULAR, an  
Arizona corporation,

19 Defendants.

PLAINTIFF'S RESPONSE TO  
DEFENDANTS' MOTION *IN LIMINE*  
**#3 TO EXCLUDE EVIDENCE OF FDA  
WARNING LETTER**

(The Honorable David G. Campbell)

(Oral Argument Requested)

21 Bard's Motion *in Limine* No. 3 [Doc. 9864] ("Motion") seeking to exclude  
22 evidence of the FDA's July 13, 2015, warning letter to Bard ("Warning Letter") on the  
23 bases of relevance, undue prejudice and hearsay should be denied.

24 **A. The Warning Letter is relevant.**

25 Bard's claim that the Warning Letter is a "red herring" is wrong. First, and most  
26 importantly, Bard vigorously opposed Plaintiffs' efforts to exclude (*see* Plaintiffs' Motion  
27 *in Limine* No. 1 [Doc. 9529]) evidence of FDA clearance or activity related to Bard's IVC  
28 filters. *See* Defendants' Response to Plaintiffs' Motion *in Limine* No. 1 [Doc. 9690].

1 Bard argued that “compliance with federal regulatory standards . . . is certainly probative  
 2 under Georgia law on the issues of reasonableness of the design, manufacture, and  
 3 warnings of the G2 Filter.” *Id.* at 2. Based on Georgia law, the Court agreed with Bard.  
 4 *See Order Denying Motion in Limine No. 1 [Doc. 9881].*

5 Given this posture, the Warning Letter is now an essential piece of evidence to  
 6 rebut Bard’s suggestion that the FDA took no action and expressed no concerns related to  
 7 its IVC filters. If Bard can use FDA’s clearance of its filter as a shield in support of its  
 8 defenses, fair play requires that Plaintiffs be allowed to use the Warning Letter to rebut  
 9 any suggestion that, once the FDA cleared the filters, it had no concerns about their  
 10 performance. The FDA’s finding that Bard failed in its reporting and handling of cases  
 11 involving filter failure in patients is of particular relevance given the nature of Plaintiffs’  
 12 claims concerning failure rates and comparative product performance.<sup>1</sup>

13 Bard’s argument that the Warning Letter is irrelevant since it is not a “final agency  
 14 determination” is equally flawed. The FDA’s position is that:

15       Warning Letters are issued only for violations of regulatory  
 16 significance. Significant violations are those violations that  
 17 may lead to enforcement action if not promptly and adequately  
 18 corrected. A Warning Letter is the agency’s principal means of  
 19 achieving prompt voluntary compliance with the Federal Food,  
 20 Drug, and Cosmetic Act (the Act).

21       FDA Regulatory Procedures Manual, Exhibit 1, at § 4-1-1. Warning letters are direct  
 22 communications with device manufacturers designed to ensure compliance. The fact that  
 23 Bard may have avoided further action does not render the FDA’s findings of violations  
 24 irrelevant or inadmissible, particularly when Bard is expected to open the door relating to  
 25 FDA clearance and regulation of its devices. *See Sadler v. Advanced Bionics, Inc.*, 2013  
 26 WL 1311148 at \*1-2 (W.D. Ky. 2013) (FDA warning letter relevant and admissible).  
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28 <sup>1</sup> This is true regardless of whether Dr. D’Ayala relied on MAUDE database information  
 in electing to use the G2 filter for Ms. Booker.

1           **B. The Warning Letter is not unduly prejudicial.**

2           Given Bard's arguments relating to Plaintiffs' *Cisson* motion, Bard can hardly be  
 3 heard now to complain of undue prejudice from Plaintiffs introducing evidence of the  
 4 Warning Letter in response to Bard's evidence concerning FDA clearance and regulation  
 5 of its filters. Any prejudice due to evidentiary heft the jury places on a regulatory  
 6 agency's determinations is invited by Bard. The same goes for Bard's contention that it  
 7 would be required to spend an inordinate amount of time to place the Warning Letter in  
 8 context. Motion at 3. Any time spent placing the Warning Letter "in proper context"  
 9 pales in comparison to the amount of time Plaintiffs will spend placing other FDA actions,  
 10 including clearance of the devices for market, "in proper context." Moreover, Bard's  
 11 acknowledgment that it can put such evidence into context for the jury ameliorates any  
 12 risk of undue prejudice. *See Sadler*, 2013 WL 1311148 at \*1-2 ("[Defendant] will have  
 13 ample opportunity to show that the statements in the documents are mere observations.").

14           **C. The Warning Letter is a Public Record and Admissible.**

15           Under Rule 803(8), a public record such as the Warning Letter may be admitted as  
 16 a hearsay exception as long as it "contains factual findings and satisfies [the]  
 17 trustworthiness requirement." *Sabel*, 737 F.Supp. at 142.<sup>2</sup> Before it can issue a warning  
 18 letter, the FDA considers whether (1) evidence shows that a product is in violation of law  
 19 or regulations and failure to correct the violation may result in enforcement action; and (2)  
 20 the violations are of regulatory significance. Exhibit 1 at § 4-1-3. These factors  
 21 demonstrate that, while the FDA is not making a final determination when it issues a  
 22 warning letter, it is providing (1) factual findings taken from an examination performed

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23           <sup>2</sup> While district courts are divided on the issue, many have held that FDA warnings, like  
 24 the Warning Letter, are admissible under the public records hearsay exception in Rule  
 25 803(8). *See Guthrie v. Ball*, 2014 WL 5314576 at \*4 (E.D. Tenn. 2014); *Musgrave v.*  
*Breg, Inc.*, 2011 WL 4502032 at \*6 (S.D. Ohio 2011) ("These portions of  
 26 the FDA bulletins fall within the hearsay exception defined by Rule 803(8) because they  
 27 are statements directly from the FDA 'setting forth matters observed pursuant to duty  
 28 imposed by law as to which matters there was a duty to report'"') (quoting Rule  
 803(8)); *Sabel*, 737 F.Supp. at 135.

(2) in the course of its administrative role—both of which place the warning letters within the public records hearsay exception articulated in Rule 803(8). *See Sadler*, 2013 WL 1311148 at \*1-2 (finding that FDA warning letter was within the Rule 803(8) hearsay exception; “FDA officials conducted the investigation themselves as a neutral party with motivations to protect public health and safety. Therefore, the Court finds these documents sufficiently reliable to be excepted from the hearsay rule”).<sup>3</sup>

For these reasons, evidence concerning the Warning Letter is admissible.

RESPECTFULLY SUBMITTED this 2<sup>nd</sup> day of February, 2018.

## GALLAGHER & KENNEDY, P.A.

By: /s/ *Mark S. O'Connor*

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## **CERTIFICATE OF SERVICE**

I hereby certify that on this 2<sup>nd</sup> day of February, 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti

<sup>3</sup> Some of the cases Bard cites in support of its claims of inadmissibility are distinguishable. For instance, in *Ortho-McNeil-Janssen Pharmaceuticals, Inc. v. State*, the decision in that case turned on divergent language in Arkansas' version of Rule 803 to exclude a DDMAC warning letter. 432 S.W.3d 563, 579-80 (Ark. 2014). Moreover, three justices joined in a dissenting opinion that noted it was “apparent” the warning letter fell “clearly within the public-records exception.” *Id.* at 581.